



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.       | CONFIRMATION NO.       |
|---|-------------|----------------------|---------------------------|------------------------|
| 10/516,389  | 06/09/2005  | Stanley Frinak       | 0256.00004                | 4725                   |
| 7590 04/01/2008   |             |                      |                           |                        |
| Amy E Rinaldo<br>Kohn & Associates<br>Suite 410<br>30500 Northwestern Highway<br>Farmington Hills, MI 48334 |             |                      | EXAMINER<br>SAIDI, AZADEH |                        |
|   |             |                      | ART UNIT<br>3735          | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>04/01/2008   | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/516,389

**Applicant(s)**

FRINAK ET AL.

**Examiner**

Anita Saidi

**Art Unit**

3735

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 6 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 6 and 10-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

1. This office action is responsive to applicant's arguments filed on February 13, 2008. The examiner acknowledges the amendments to claims 1, 6 and 10 and the cancellation of claims 3, 5, 17, 22 and 23. Currently claims 1-2, 6, 10-16 are pending.
2. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

### ***Response to Arguments***

3. Applicant's arguments, see page 4, lines 11-21 filed on February 13, 2008, with respect to rejection of claims 3-5 under 35 USC 112 second paragraph and claims 17, 22-23 under 35 USC 101 have been fully considered and are persuasive. The rejection of claims 3-5, 17 and 22-23 has been withdrawn.
3. Applicant's arguments, see page 6, lines 14-28 and pages 7-9, filed on February 13, 2008, with respect to the rejection(s) of claim(s) 1-3, 5-6, 10-17 and 22-23 under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found art and new interpretation of the claims.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 10-12 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,623,443 to Polaschegg.

In reference to claims 1, 10-12 and 14:

Polaschegg teaches a method and device for detection of stenosis in extracorporeal blood pressure measurement (Abstract). The stenosis, such as a graft or fistula, in a blood access circuit or in an extracorporeal circuit is detected by monitoring the pressure pulses in the extracorporeal circuit. Sensors mechanically attached to the wall of the blood tubing will monitor the pressure pulse amplitude (Abstract). The pressure at the vicinity of the fistula, such as at arterial puncture site (201) and at the venous puncture site (203), is monitored via pressure sensors (40 and 42) continuously (Col. 3, lines 1-10 and Col. 4, lines 41-53). The derived intravascular blood pressure is compared to a

standard, during a procedure such as blood dialysis (Col. 8, lines 20-55). The deviation of a pressure pulse amplitude signal from a predetermined value indicates stenosis (Abstract).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2, 6, 13 and 15-16 and rejected under 35 U.S.C. 103(a) as being unpatentable over Polaschegg in view of US 4,710,164 to Levin et al (Hereinafter "Levin").

In reference to claims 2, 6 and 13:

Polaschegg teaches all of the claim limitations; see the rejection of claims 1 and 10 above.

However, Polaschegg fails to teach that:

A microprocessor is used to analyze the data where the derived intravascular blood pressure is compared to a standard using an algorithm.

Levin teaches:

An automated hemodialysis system and method of use thereof, where the system continuously monitors patient's blood pressure during a hemodialysis procedure (Abstract of Levin). The system monitors the blood pressure in order to detect any extreme changes in the patient's blood pressure. If the blood pressure falls below a threshold an alarm will be activated (Abstract of Levin). The blood pressure system of Levin is attached to a microprocessor (10 of Levin) which controls the hemodialysis machine, as well as monitoring the blood pressure. The microprocessor is preprogrammed with high and low blood pressure alarm limits which may be modified from an operator control panel. The microprocessor is also preprogrammed to detect deviation of blood pressure from initial readings obtained and stored at the onset of dialysis (Col. 3, lines 44-48 and Col. 4, lines 46-68 of Levin).

It would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have used a microprocessor configured similar to the one taught by Levin in a stenosis detection device similar to that of Polaschegg in order to monitor the extracorporeal blood pressure and for controlling the dialysis machine.

In reference to claims 15 and 16:

A communication means (cable/electronic communication for connecting the display to the dialysis machine of Levin) is connected to the device for communicating a warning when the device indicates an irregularity of the intravascular blood pressure for at least two uses of the device (Col. 4, lines 18-22 of Levin).

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,828,543 to Weiss et al discloses an extracorporeal circulation apparatus. US 5,453, 576 to Krivitski discloses cardiovascular measurements by sound velocity dilatation.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anita Saidi whose telephone number is (571)270-3001. The examiner can normally be reached on Monday-Friday 9:30 am - 6:00 pm Est..  
  
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/  
Supervisory Patent Examiner  
Art Unit 3735

/A. S./  
Examiner, Art Unit 3735  
4/1/2008